

Third Circuit Holds FTC Must Show Defendants Are 'About to Violate' the Law for Injunctive Relief and Disgorgement

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On February 25, 2019, in *FTC v. Shire ViroPharma, Inc.*, the U.S. Court of Appeals for the Third Circuit confirmed that the Federal Trade Commission (FTC) cannot plead its way into federal court via Section 13(b) of the FTC Act in the absence of specific allegations that a defendant “is violating, or is about to violate” a law enforced by the FTC. Highlighting the absence of such allegations from the FTC’s complaint, the Third Circuit’s affirmance of the lower court’s dismissal blocked the agency from seeking a permanent injunction against brand-name pharmaceutical company Shire ViroPharma (Shire) as well as other equitable relief, including disgorgement. The FTC had sought to enjoin Shire from employing tactics that Shire had allegedly used to prevent generic drugs from competing with one of its branded products. The agency had also sought disgorgement of Shire’s allegedly ill-gotten profits.

The Third Circuit’s ruling is almost certain to influence the FTC’s investigative tactics and prosecutorial strategy going forward. FTC staff will undoubtedly feel additional time pressure to complete investigations where the defendant’s conduct is likely to have ceased (or could cease), before a complaint can be filed. In addition, while the facts demonstrating the cessation of allegedly anti-competitive conduct were clear in *Shire*, other factual circumstances might present a closer call, emboldening the agency to take its chances in federal court. (Notably, the Third Circuit pointedly declined to specify the “outer reach” of the phrase “about to violate.”) Moreover, the Third Circuit’s decision is of course binding only within the Third Circuit, which may lead the FTC to re-evaluate its choice of forum in future cases. Finally, the ruling does not disturb the FTC’s ability to initiate in-house administrative proceedings, and it may in fact result in an uptick in such activity.

FTC v. Shire ViroPharma

The FTC filed a complaint against Shire in the U.S. District Court for the District of Delaware in February 2017, accusing the company of having violated Section 5 of the FTC Act. The complaint alleged that Shire engaged in unfair methods of competition by abusing the Food and Drug Administration’s (FDA) approval procedures and petitioning process to insulate its branded antibiotic Vancocin from generic pharmaceutical competition. Specifically, the FTC accused Shire of engaging in a sham petitioning campaign from 2006 to 2012 by submitting numerous meritless filings to both the FDA and the courts, causing delayed FDA approval of generic Vancocin capsules that would compete with Shire’s branded product. The FTC’s complaint requested that, in order to prevent the alleged harm from occurring in the future, the court permanently enjoin Shire under Section 13(b) from engaging in this type of conduct. The complaint also requested that the court order restitution and disgorgement of the company’s allegedly ill-gotten gains reaped from delaying the entry of generic alternatives.

The district court granted Shire’s motion to dismiss the FTC’s complaint in March 2018. The court held that the FTC failed to plead facts sufficient to show that Shire “is violating, or is about to violate” the law, a prerequisite imposed by the plain text of Section 13(b) for the agency to sue in federal district court. On appeal, a Third Circuit panel agreed, noting that Shire’s alleged misconduct ceased nearly five years before the FTC filed its complaint. (Shire had also divested Vancocin before the complaint was filed.) In fact, the panel found that the only allegations regarding whether Shire was “about to violate” the law were general ones: that Shire had the ability and incentive to repeat the same type of behavior with its other branded pharmaceutical products. In the panel’s view, such allegations were “woefully inadequate” to meet Section 13(b)’s

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“about to violate” standard. Without elaborating on what factual allegations would in fact suffice to meet this standard, the panel explained that “‘about to violate’ means something more than a past violation and a likelihood of recurrence.” The Third Circuit was unmoved by the FTC’s “parade of horrors” argument — namely, that such an interpretation thwarts the agency’s congressionally assigned law enforcement objectives since wrongdoers could avoid an FTC lawsuit in federal court by ceasing their conduct upon learning of the agency’s investigation. Brushing aside these concerns, the panel noted that the agency could still pursue administrative remedies against potential defendants for past violations of the law.

Potential Implications

One question is whether the Third Circuit’s reasoning in *Shire* will be adopted in other jurisdictions, as broad acceptance could impact the FTC’s ability to pursue its most potent remedies in federal court. The agency’s decision to file its complaint in the District of Delaware — rather than seek an in-house administrative remedy via Section 5(b) against *Shire* — was undoubtedly influenced by the enhanced relief available in federal court as compared to the administrative process, which can be cumbersome and offers more limited remedies.

When the FTC seeks to challenge unfair methods of competition via its in-house procedures, it begins by issuing an administrative complaint under Section 5(b). This complaint triggers a hearing before an FTC administrative law judge (ALJ), whose ruling can be appealed to the commission. If the commission believes the law has been violated after reviewing the ALJ’s decision, it serves the defendant with a cease-and-desist order (which can be directly appealed to an appropriate federal circuit court). Should the defendant violate the commission’s order, the FTC would have to seek a court’s aid to enforce that order. Section 5 of the FTC Act authorizes the agency to seek civil penalties of up to \$42,530 (adjusted annually for inflation) per violation of its orders.

By contrast, Section 13(b) allows the FTC to proceed directly to federal district court to obtain an injunction, temporary restraining order or other forms of equitable relief, which can include disgorgement of unjust enrichment and restitution for injuries suffered by consumers. These are some of the most powerful remedies available to the FTC, and, according to the agency, the availability of these remedies has helped it secure some of its most significant settlements. Indeed, in its appellate briefing, the FTC pointed to Section 13(b) as a critical factor in securing settlements related to the Volkswagen emissions scandal, which the agency claims resulted in over \$8 billion being returned to American consumers. In making this point, the agency acknowledged that it likely could not have used Section 13(b) and obtained this relief under the district court’s reading of the law in *Shire*.

While the FTC may have been denied its preferred recourse in *Shire*, federal courthouse doors across the country have not necessarily been closed to the agency. In particular: (i) the Third Circuit deliberately declined to define the boundaries of the phrase “about to violate the law”; (ii) this precedent is binding only in the Third Circuit; and (iii) in any event, the FTC continues to have administrative proceedings at its disposal.

Nevertheless, in the wake of *Shire*, the FTC may perceive greater pressure to conduct investigations and bring cases more quickly. The roughly five-year gap between when *Shire*’s alleged illicit conduct ceased and when the FTC filed its complaint proved to be a significant hurdle in the agency’s case. The FTC had to concede that *Shire* was not currently violating the law, and it was left to argue — ultimately unsuccessfully — that *Shire*’s alleged past violation and a reasonable likelihood of recurrent future violations satisfied Section 13(b)’s “about to violate the law” requirement. Following *Shire*, we expect the FTC staff to seek to expedite their investigations. Companies should anticipate that the FTC will issue broader requests for documents and information, with potentially less flexibility to negotiate the scope and timing of their responses.